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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/612,404 07/07/00 BARRY

G MONY: 140

EXAMINER

HM22/0509

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ART UNIT	PAPER NUMBER
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1652

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DATE MAILED:

05/09/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No. 09/612,404	Applicant(s) Barry et al.
Examiner Manjunath N. Rao	Art Unit 1652

— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on Feb 20, 2001
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle* 1035 C.D. 11; 453 O.G. 213.
- Disposition of Claims**
- 4) Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above, claim(s) 19 and 20 is/are withdrawn from consideration.
- 5) Claim(s) 4, 7, 10, and 16 is/are allowed.
- 6) Claim(s) 1-3, 5, 6, 8, 9, 11-15, 17, and 18 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) All b) Some* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) Notice of References Cited (PTO-892) 18) Interview Summary (PTO-413) Paper No(s). _____
- 16) Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) Notice of Informal Patent Application (PTO-152)
- 17) Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 20) Other: _____

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DETAILED ACTION

1. Claims 1-20 are still pending in this application. Claims 19-20 remain withdrawn from consideration (see previous Office action). Claims 1-18 are now under consideration.

2. Applicants' arguments filed on 2-20-01, paper No. 8, have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
4. Claims 1-3, 5-6, 8, 9, 11-12, 14-15, 17-18 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for DNA with SEQ ID NO:4, 6, 7, 8 and 17 encoding a protein having glyphosate oxidoreductase activity, does not reasonably provide enablement for any DNA that is capable of hybridizing to the above SEQ IDs under any hybridization conditions. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

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Claims 1-3, 5-6, 8, 9, 11-12, 14-15, 17-18 are so broad as to encompass any DNA encoding glyphosate reductase from any source. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of DNA sequences that are broadly encompassed by the claims.

Since the amino acid sequence of a protein determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and to obtain the desired activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the proteins' structure relates to its function. However, in this case the disclosure is limited to the DNA sequences with SEQ ID NO:4, 6, 7, 8 and 17.

Furthermore, applicants do not provide specific hybridizing conditions under which the isolated DNA molecule can hybridize to the target sequences. Since the nucleotide sequence determines the type of protein and the ultimate function of the encoded protein and since only nucleic acids with very high percent homology capable of hybridizing under highly stringent conditions can be used for such a function, obtaining the nucleotide sequences as proposed by the applicants (any DNA from any source hybridizing to SEQ ID NO:4, 6, 7, 8 and 17 under any hybridizing conditions) may not lead to desired function of the polynucleotides. This is because hybridization of the isolated DNA molecule under any condition (low, medium or high stringent

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conditions) to the target molecule will result in an enormous number of nucleotide sequences that may or may not hybridize specifically to SEQ ID NO:4, 6, 7, 8 and 17.

While many recombinant techniques are known, it is not routine in the art to screen for multiple substitutions or modifications of nucleotides, as encompassed by the instant claims, and the base changes within a nucleic acid's sequence can be made with a reasonable expectation of success in obtaining the desired activity/utility are limited and the result of such modifications is unpredictable. In addition, one skilled in the art would expect any tolerance to modification for a given DNA to diminish with each further and additional modification, e.g. multiple substitutions.

The specification does not support the broad scope of the claims which encompass all DNA encoding a protein having glyphosate oxidoreductase activity because the specification does not establish: (A) a method of isolation of DNA encoding a glyphosate oxidoreductase solely based on hybridization to a target DNA under any hybridization condition; (B) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including any DNA encoding glyphosate oxidoreductase enzyme. The scope of the claims must bear a reasonable correlation with the scope of enablement (*In re Fisher*, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance about the specific hybridization conditions under which an isolated DNA can hybridize to a target DNA encoding glyphosate

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reductase enzyme, determination of DNAs having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

In response to the rejection of the above claims under 35 U.S.C., 112, 2nd paragraph in the previous Office action, applicants have traversed rejection by arguing that an individual of ordinary skill in the art is aware of the number of methods that exist for the identification of recombinant clones which rely upon DNA-DNA hybridization and that the specification provides a reference (Maniatis et al. 1982) at page 16, lines 25-26 in which the methods are described and that the above reference is widely used by those skilled in the art. While Examiner agrees that Maniatis et al. is a widely used reference which provides the general methodology for techniques in molecular biology, a perusal of the specification at page 16 (column 16, lines 25-26) makes no reference to Maniatis et al. Furthermore, the reference is not fully incorporated into the specification. Therefore, applicants argument that the specification supports the hybridization conditions through the above reference is misplaced. Also the claims are drawn to specific hybridization of specific DNA sequences but the above reference provides a general methodology for setting up hybridization reaction for any DNA. Applicants concede that some "optimization of hybridization and washing conditions is required". These conditions are not provided either in the specification or in the above reference for the above specific DNA. Applicants reference to PCR conditions for hybridization conditions is also highly misplaced as

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PCR experiments and hybridization experiments are two separate experiments and conditions for one cannot be simply applied to the other.

As is well known to one of ordinary skill in the art, hybridization experiments can be performed either at low stringency, medium stringency or high stringency. Without a specific or defined stringency condition Examiner contends that the claims may read on any gene encoding a glyphosate oxidoreductase. This is because when hybridization is performed under low stringency the isolated DNA of the claims will read on a broad set of glyphosate oxidoreductase genes that may not be highly homologous to the DNA sequences in the instant application and on the same lines if the hybridization is performed under high stringency conditions then the isolated DNA of the claims will read on a narrow set of glyphosate oxidoreductase genes.

Absent a statement of hybridization conditions, the claims read on any gene encoding a glyphosate oxidoreductase. Applicants point out that the specification clearly indicates another approach for cloning additional novel glyphosate oxidoreductase genes. Applicants also list other methods that they have provided in the specification. However, this argument is still not persuasive because the claims are not drawn to other methods of identifying glyphosate oxidoreductase genes.

Applicants also argue that the DNA claimed represents a very powerful tool for further identification through hybridization methods well known in the art, of homologous glyphosate oxidoreductase enzymes with altered properties. Examiner disagrees. While applicants have

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provided a DNA molecule that encodes glyphosate oxidoreductase, they have not provided specific hybridization conditions under which the experiment can be performed.

Double Patenting

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 13-15 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 13 of U.S. Patent No. 5,463,175. Although the conflicting claims are not identical, they are not patentably distinct from each other because Claims 13-15 of the instant application claims the same SEQ ID NO:8 claimed in claim 13 of the patent.

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Allowable Subject Matter

7. Claims 4, 7, 10, and 16 are allowable.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Manjunath Rao whose telephone number is (703) 306-5681. The Examiner can normally be reached on M-F from 6:30 a.m. to 3:00 p.m. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, P.Achutamurthy, can be reached on (703) 308-3804. The fax number for Official Papers to Technology Center 1600 is (703) 305-3014. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Manjunath N. Rao

May 7, 2001



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